DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 21, 2015

Spectra Medical Devices
Mr. Agustin Turriza
Operations Manager
260-F/H Fordham Road
Wilmington, Massachusetts 01887

Re: K142791
Trade/Device Name: Spectra Soft Tissue Biopsy Needles
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: October 21, 2014
Received: October 23, 2014

Dear Mr. Turriza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142791

Device Name
Spectra Medical Devices, Inc.

Indications for Use *(Describe)*

Device Name: Spectra Soft Tissue Biopsy Needles:
Chiba Soft Tissue Biopsy Needle / Fine Needle Aspiration Biopsy Needle
Franseen Soft Tissue Biopsy Needle
Westcott Soft Tissue Biopsy Needle
Turner Soft Tissue Biopsy Needle
Greene Soft Tissue Biopsy Needle

Indications For Use:

Spectra Soft Tissue Biopsy Needles are indicated for obtaining biopsy samples from soft tissue in percutaneous or open surgical procedures from various tissues through a combination of cutting and/or aspirating in such a manner that the biopsy sample is retained in the orifice of the needle.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(21 CFR 807.92)

for *Spectra Soft Tissue Biopsy Needles*

SUBMITTER:

Spectra Medical Devices, Inc.
260-F/H Fordham Road
Wilmington**,** Massachusetts, 01887

ESTABLISHMENT REGISTRATION NUMBER:

1224960

CONTACT:

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DATE PREPARED:

September 23, 2014

SUBMISSION DEVICE:

Trade Name:	***Spectra Soft Tissue Biopsy Needles***
Regulation Name:	Gastroenterology-urology biopsy instrument
Common/Usual Name:	Soft Tissue and Fine Needle Biopsy Needles
Classification Panel:	Gastroenterology/Urology
Review Advisory Committee:	General & Plastic Surgery
Regulatory Class:	Class II
Product Code:	KNW
Regulation Number:	21 CFR § 876.1075

The following predicate devices have not been the subject of a design related recall.
No reference devices were used in this submission.

PREDICATE DEVICE:

Trade Name:	**Manan Soft Tissue Biopsy Needles K980122**
Regulation Name:	Gastroenterology-urology biopsy instrument
Common/Usual Name:	Manual biopsy needles for soft tissues
Classification Panel:	Gastroenterology/Urology
Review Advisory Committee:	General & Plastic Surgery
Regulatory Class:	Class II
Product Code:	KNW
Regulation Number:	21 CFR § 876.1075

Trade Name:	**Quick-Core™ Biopsy Needle K973565**
Regulation Name:	Gastroenterology-urology biopsy instrument
Common/Usual Name:	Soft Tissue Biopsy, puncture and aspiration cannulas and needles
Review Advisory Committee:	General & Plastic Surgery
Regulatory Class:	Class II
Product Code:	KNW
Regulation Number:	21 CFR § 876.1075

DEVICE DESCRIPTION:

The Spectra Soft Tissue and Aspiration Biopsy Needles consist of a stainless steel needle and a translucent standard female Luer locking hub. A stylet cap/stylet rod assembly mates with the needle hub assembly. A depth stop is integral with each needle type to facilitate depth placement. The needle assembly is covered by a translucent removable needle guard. The needles are available in a range of wall thicknesses, gauges and lengths to match the end-user need. Needles are available with an echogenic treatment to help ensure strong reflection during ultrasound procedures.

Spectra Soft Tissue Biopsy Needles will be marketed as sterile, non-pyrogenic, and single use devices.

INTENDED USE:

The Spectra Soft Tissue Biopsy Needles are intended to be used by medical professionals to obtain biopsy samples from soft tissue in percutaneous or open surgical procedures from various tissues through a combination of cutting and/or aspirating in such a manner that the biopsy sample is retained in the orifice of the needle.

INDICATIONS FOR USE:

Device Name: Chiba Soft Tissue Biopsy Needle / Fine Needle Aspiration Biopsy Needle
Franseen Soft Tissue Biopsy Needle
Greene Soft Tissue Biopsy Needle
Turner Soft Tissue Biopsy Needle
Westcott Soft Tissue Biopsy Needle

The Spectra Soft Tissue Biopsy Needles are indicated for obtaining biopsy samples from soft tissue in percutaneous or open surgical procedures from various tissues through a combination of cutting and/or aspirating in such a manner that the biopsy sample is retained in the orifice of the needle.

The Indications for Use statement for the Spectra Soft Tissue Biopsy Needles is not identical to those of the predicate devices; however, the differences do not alter the intended use of the device nor do they affect the safety and efficacy of the device relative to the predicate. Both the submission and predicate devices have the same intended use.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

The Spectra Soft Tissue Biopsy Needles utilize substantially equivalent technological elements compared to the predicate devices used in this submission:

- the Spectra Soft Tissue Biopsy Needles are manual soft tissue biopsy needles
- they use substantially equivalent materials
- they are sterilized using ethylene oxide
- same fundamental design: plastic injection molded hub, a stainless steel stylet secured in a stylet, a stainless steel cannula, echogenic options, industry-standard grinding and bevel designs
- same method of operation
- no change in patient population
- no change in clinical context
- no change in intended use

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the cap was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995. The submission device and predicate devices are identical. The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity
- Hemocompatibility

Other performance tests

Physical tests were performed to ensure that the Spectra Soft Tissue Biopsy Needles had standard ISO Luer hubs with applicable luer testing using ISO 594. Needle bond strength tests with hubs were also conducted. The Spectra Soft Tissue Biopsy Needles passed all tests.

CONCLUSION

The Submission Devices, Spectra Soft Tissue Biopsy Needles, have met all established acceptance criteria for performance testing. The Submission Device is substantially equivalent to the predicate device in terms of intended use, design, materials, operation, function, and sterilization method. This demonstrates that the Submission Devices are safe and effective for the intended use, and based on FDA's 510(k) Decision-Making Flowchart is substantially equivalent to the indicated Predicate Devices:

- Manan Soft Tissue Biopsy Needles K980122
- Cook, Inc. Quick Core Soft Tissue Biopsy Needle K973565